

BOTANICALS

Drug or food?

Botanicals are used in food incl. supplements and in herbal medicinal products. Both categories are fundamentally different when it comes to regulations (Directive 2002/46/EC, Directive 2004/24/EC amending Directive 2001/83/EC, respectively).

The use of plants as food is usually regulated by specific national rules. Some Member States have adopted national legislation for plants used as foods, mainly through "positive" and "negative" lists. Important for supplements is the Claim Regulation ((EC) No 1924/2006). Although the evaluation process for botanical claims under the Claim Regulation is currently on hold, there are ways to differentiate your product from others.

For botanicals in herbal medicinal products, the most common way for market entry is a simplified registration, either as Traditional Herbal Medicinal Product (THMP) or as Well-Established Use (WEU) product. Both have their regulatory specifics.

OUR SERVICES INCLUDE

- Gap analyses of existing documentation
- Development of the optimum regulatory strategy

For botanicals in medicinal products

- Drawing up and/or updating of the Common Technical Document (CTD)
- Pharmacological, toxicological and clinical expert statements
- Proof of tradition for Traditional Herbal Medicinal Products (THMP)
- Preparation of and assistance with meetings with drug authorities
- Consultation in drug safety (pharmacovigilance) and life cycle of your products
 - Drawing up of PSURs (Periodic Safety Update Reports)
 - Compilation of risk management plans (RMPs)

For botanicals in food

- Marketability check for EU countries including demarcation between food and drug
- Claim strategy to support clients in finding attractive pending botanical claims
- Label check and notification procedure for food supplements
- Novel food dossier compilation if needed



TRADITIONAL HERBAL MEDICINAL PRODUCT (THMP)

To qualify for the simplified registration procedure as a traditional herbal medicinal product, the following is required:

- Safe medical use for at least 30 years (of which 15 years were in the EU) must be substantiated (proof of traditional use)
- THMPs are intended to be used without the supervision of a medical practitioner, therefore only certain indications are allowed
- Only oral, external dosage or inhalation forms are accepted
- Quality must be in accordance with the European regulations

USING ON-HOLD CLAIMS FOR BOTANICALS IN FOOD

Pending botanical claims (On-Hold-Claims) can be used until EFSA decides how to evaluate the botanical claims. Some particulars to be taken into account are:

- The claim wording must be in alignment with the Health Claims Regulation (e.g. no medical claims)
- The plant part for which the pending claim was made as well as the wording, the health relationship, and the conditions of use must be the same as for the pending claim
- Clinical evidence should support the claim wording
- Scientific substantiation of the used pending claim

Botanicals are used in food and herbal medicinal products. Both categories are fundamentally different when it comes to regulations. Based on your product strategies, a&r supports you in navigating and meeting specific requirements and legislations.

We help to upgrade your existing THMP files or to compile your new THMP dossiers.

Our expertise in pending botanical health claims can facilitate the regulatory assessment of your differentiated, innovative food products.

CONTACT US

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